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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,434	12/12/2001	Mark K. Hechinger	1007-109.US	4955

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,434

Applicant(s)

HECHINGER, MARK K.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 6-11 in the reply filed on 10/27/04 is acknowledged. The traversal is on the ground(s) that Groups I and IV are sufficiently related to Group II. This is not found persuasive because of reasons set forth in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 8, 10, and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s) or amend the claim(s) to place the claim(s) in proper dependent form. Claims 8, 10, and 11 recite the "An assay as claimed in claim 6"; however, claim 6 is drawn to an assay kit. Claims 8, 10, and 11 all recite method steps involved in the assay, which do not merit patentable weight in claims drawn to a kit, but do not further limit the kit in any way.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term "commonly" in claim 6 is a relative term which renders the claim indefinite. The term "commonly" is not defined by the claim, the specification does not provide a standard

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for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

6. Claim 6 is rejected as vague and indefinite for the recitation of "so-called rheumatic disease." With this terminology, it is unclear which diseases are included and excluded from the claim.

7. Claim 6 is rejected as vague and indefinite for the recitation of "particle sized latex bead" in step (a). Since particles may be of different sizes, the size requirement of the limitation is unclear. In addition, the recitation of "sizes" in step (a) renders the claim vague, as step (a) only requires one bead.

8. Claim 7 recites the limitation "beads with antigens coated on the surface" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 9 is rejected as vague and indefinite for the recitation of "designed to simultaneous detect" because it is unclear how the kit has been designed for this purpose.

10. Claim 10 is rejected as vague and indefinite for the recitation of "so-called rheumatic disease." With this terminology, it is unclear which diseases are included and excluded from the claim. In addition, the recitation of a "fluorescent conjugate" renders the claim vague and indefinite because the composition of the conjugate has not been recited.

11. Regarding claim 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

12. The term "well" in claim 10 is a relative term which renders the claim indefinite. The term "well" is not defined by the claim, the specification does not provide a standard for

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ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

13. The term "appropriate" in claim 11 is a relative term which renders the claim indefinite. The term "appropriate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

14. The term "well" in claim 11 is a relative term which renders the claim indefinite. The term "well" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

15. Claim 11 is also rejected as vague and indefinite for the recitation of a "fluorescented conjugate" because the composition of the conjugate has not been recited.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (US Pat. 5,286,452) in view of McHugh et al. (Clin. Imm., 1991), Ngo et al. (US Pat. 4,977,077), Victor et al. (US Pat. 5,573,911), and Schwartz et al. (US Pat. 5,380,663).

Hansen teaches the use of multiple-sized spherical latex particles either coated with or mixed with specific antigens or antibodies in order to detect multiple analytes from a sample (Col. 13, lines 13-30). The particles range in size from 0.02uM to 12uM (Col. 12, lines 35-68). Buffer containing BSA may be used to block the non-specific binding sites on the beads (Col. 13, line 67; Col. 14, line 48). The reference also teaches that the invention may be used with any known antigen-antibody combination and is not limited to its specific examples (Col. 13, lines 13-30). However, the reference does not teach FITC, carbonate and bicarbonate buffer, the specific antigens of the claims, and the use of a kit.

McHugh et al. teach the use of microspheres that are less than 10uM in diameter for multi-analyte assays. The reference teaches the use of fluorescein isothiocyanate conjugated goat anti-human IgG or IgM for to detect the microspheres. The reference teaches the use of multiple microspheres, each coated with a different antigen (pages 60-63). However, the reference does not teach carbonate and bicarbonate buffer, the specific antigens of the claims, and the use of a kit.

Ngo et al. teach an immunoassay, wherein beads are prepared for use as the solid phase of the immunoassay by rinsing in sodium bicarbonate solution, followed by immersion anti-drug antibody in sodium carbonate buffer. After several more risings, the beads were ready for use

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(Col. 7). However, the reference does not teach the specific antigens of the claims or the use of a kit.

Victor et al. teach an immunoassay for the simultaneous detection of autoimmune antibodies to multiple antigens, such as SS-A, SS-B, and Scl-70 (Col. 4). However, the reference does not teach the use of a kit.

Schwartz et al. teach a kit comprising antibody-coated beads for use with a flow-cytometer (Col. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to label the beads/microspheres of Hansen with fluorescein isothiocyanate conjugated goat anti-human IgG, as taught by McHugh et al. because labels are routinely used for optical detection, and one of ordinary skill in the art would have known that any label could have been used with the method of Hansen with a reasonable expectation of success. It would have further been *prima facie* obvious to use sodium carbonate and sodium bicarbonate as taught by Ngo et al. with the modified method of Hansen and McHugh et al. because Ngo et al. teach these buffers are well suited for coating beads with receptors, thereby providing one with a reasonable expectation of success in doing so. Also, depending on the material that one wished to coat on the beads, one would have known the appropriate buffer to use. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would also have been *prima facie* obvious to detect one or more of SS-A, SS-B, and Scl-70 with their corresponding antibodies, as taught by Victor et al. because Hansen is generic with respect to the antigen/antibody combinations that could be used with their reference, stating that

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any known combination is suitable. Finally, it would have been *prima facie* obvious to package all the components necessary to carry out the modified method of Hansen, McHugh et al., Ngo et al., and Victor et al. into a kit, as taught by Schwartz et al. because a kit provides a convenient way to store all the required reagents for an assay together, thereby increasing ease of use and the efficient allocation of resources.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 6-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,159,748. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a fluorescent immuno-bead assay kit for detection of antinuclear antibodies comprising latex beads of similar sizes, the same antigens and anti-antigens, goat anti-human IgG F(ab')²-[FITC], sodium carbonate, sodium bicarbonate, and bovine serum albumin, and one of ordinary skill in the art would realize that the two sets of claims read on each other.

Conclusion

Claims 6-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

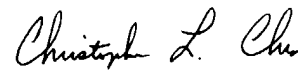
The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641




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PRIMARY EXAMINER
GROUP 1800 / 641
12/9/04